

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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REC'D 3.1 MAR 2006
WIPO

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

29 MAR 2006

| | | |
|---|--|--|
| Applicant's or agent's file reference 0032.0007WO1 | | FOR FURTHER ACTION See paragraph 2 below |
| International application No. PCT/US05/34606 | International filing date (day/month/year) 29 September 2005 (29.09.2005) | Priority date (day/month/year) 29 September 2004 (29.09.2004) |
| International Patent Classification (IPC) or both national classification and IPC IPC: Please See Continuation Sheet USPC: 433/32,89,49,52,53,54,214,215,216,90 | | |
| Applicant NGA, INC. | | |

1. This opinion contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | | |
|--|--|---|
| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 16 March 2006 (16.03.2006) | Authorized officer Kevin Shaver <i>Sharon J. Cheever</i> Telephone No. (571) 272-4714 |
|--|--|---|

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/34606

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing
 table(s) related to the sequence listing

b. format of material

on paper
 in electronic form

c. time of filing/furnishing

contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/34606

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|---|-----|
| Novelty (N) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Inventive step (IS) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Industrial applicability (IA) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |

2. Citations and explanations:

Claims 1-4,9-11,16,21-22,26-28,30,32-34,38-39,41-42,49-51,53-55,68-74,86,88,98,100,114,115, and 117-118 lack novelty under PCT Article 33(2) as being anticipated by Jensen et al (USPN 6,309,625). Jensen et al disclose a method for tooth rejuvenation comprising applying to a tooth a layer of a composition comprising an aqueous solution of one or more edible acids, wherein the composition has a pH selected from a range of about 0.5 to 5 and wherein the composition does not contain peroxide. Specifically Jensen et al disclose, "the present invention relates to compositions and methods for whitening and desensitizing teeth. The present invention relates to compositions that may be applied directly to a person's teeth for shorter periods of time" (column 1, lines 7-10).

Claims 43,49-50,52,56-61,104-107,110, and 113 lack novelty under PCT Article 33(2) as being anticipated by Friedman (US 2002/0058231 A). Friedman discloses an apparatus for rejuvenating hard tissue comprising a housing with a capsule comprising an aqueous edible composition; a heating element for heating the acid composition; a temperature sensor; a control system; a power supply; and an applicator as described in paragraphs [0006]-[0012].

Claim 40 lacks an inventive step under PCT Article 33(3) as being obvious over Jensen et al in view of Friedman. Jensen et al disclose the invention as claimed but fails to disclose or reasonably suggest a heating element serving to raise a temperature of the composition to a desired temperature. This is taught by Friedman in paragraph [0010]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the heating unit as taught by Friedman into the applicator disclosed by Jensen et al in order to provide a means for heating the composition prior to application.

Claims 5-8,12-15,17-20,23-25,29,31,35-36,44-48,62-67,75-85,87,89,90-97,99,101-103,108-109,111-112, and 116 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for tooth rejuvenation comprising applying to a tooth surface a layer of composition comprising an aqueous solution of one or more edible acids, wherein the composition has a pH selected from a range of about 0.5 to 5; heating the composition to a temperature no higher than 60 degrees Celsius and; removing the composition from the tooth surface. The prior art also does not disclose a method of impregnating the porous layer of hard tissue with particles having a fluidity temperature higher than a melting temperature of a hard tissue of the porous layer; and selectively heating the porous layer to a temperature higher than the melting temperature of the hard tissue.

Claims 1-118 meet the criteria set out in PCT Article 33(4), and thus a method of rejuvenating a tooth structure of hard tissue has industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/34606

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of IPC:

A61C 5/04(2006.01),19/00(2006.01),9/00(2006.01),1/14(2006.01),11/00(2006.01),5/00(2006.01),5/04(2006.01)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes)with respect to claims 5-8, 12-15, 17-20, 23-25, 29, 31, 35, 36, 40, 44-48, 62-67, 75-85, 87, 89-97, 99, 101-103, 108, 109, 111, 112, AND 116

The opinion as to Novelty was negative (No) with respect to claims 1-4, 9-11, 16, 21, 22, 26-28, 30, 32-34, 387, 39, 41, 42, 43, 49-55, 56-61, 68-74, 86, 88, 98, 100, 104-107, 110, 113-115, 117 AND 118

The opinion as to Inventive Step was positive (Yes)with respect to claims 5-8, 12-15, 17-20, 23-25, 29, 31, 35, 36, 40, 44-48, 62-67, 75-85, 87, 89, 90-97, 99, 101-103, 108-109, 111, 112 AND 116

The opinion as to Inventive Step was negative(NO) with respect to claims 1-4, 9-11, 16, 21, 22, 26-28, 30, 32-34, 38, 39, 41-43, 49-61, 68-74, 86, 88, 98, 100, 104-107, 110, 113-115, 117 AND 118

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-118

The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/34606

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61C 5/04(2006.01),19/00(2006.01),9/00(2006.01),1/14(2006.01),11/00(2006.01),5/00(2006.01),5/04(2006.01)

USPC: 433/89,49,52,53,54,215-216,32,214,90

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/89,49,52,53,54,215-216,32,214,90

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|---|--|
| X --- Y | US 6,309,625 B1 (JENSEN et al) 30 October 2001 (30.10.2001), column 2, lines 41-49;column 8, lines 48-51;column 9, lines 40-44&49-52 & Figures 1&5. | 1-4,9-11,16,21-22,26-28,30,32-34,38-39,41-42,49-51,53-55,68-74,86,88,98,100,114-115,117-118 ----- 40 |
| X --- Y | US 2002/0058231 A1 (FRIEDMAN) 16 May 2002 (16.05.2002), [0006]-[0012] | 43,49-50,52,56-61,104-107,110,113 ----- 40 |
| A | US 2002/0072030 A1 (DAVIS) 13 June 2002 (13.06.2002), entire document. | 1-118 |



Further documents are listed in the continuation of Box C.



See patent family annex.

| | | |
|---|-----|--|
| * Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier application or patent published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | | |
| "P" document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search

01 March 2006 (01.03.2006)

Date of mailing of the international search report

29 MAR 2006

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| A | US 2004/0116511 A1 (MALIK) 17 June 2004 (17.06.2004), entire document. | 1-118 |